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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,809	02/02/2005	Koji Kawai	TIP-04-1339	9964
35811	7590	01/05/2006	EXAMINER	
IP GROUP OF DLA PIPER RUDNICK GRAY CARY US LLP			GEMBEH, SHIRLEY V	
1650 MARKET ST			ART UNIT	
SUITE 4900			PAPER NUMBER	
PHILADELPHIA, PA 19103			1614	

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/520,809	Applicant(s) KAWAI ET AL.	
	Examiner Shirley V. Gembeh	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-6 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

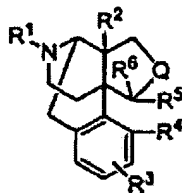
Election/Restrictions

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

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A therapeutic or prophylactic agent for preventing nausea and vomiting, the agent comprising a morphinan derivative represented by general formula (I):



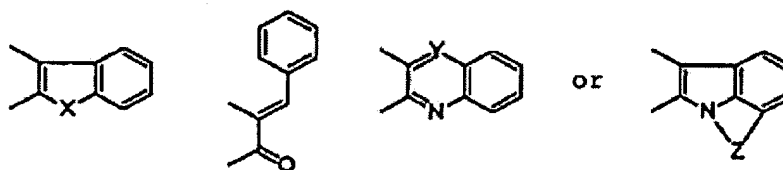
(I)

or a pharmacologically acceptable acid addition salt thereof as an active ingredient,

[where R¹ represents a hydrogen atom, an alkyl group having 1 to 5 carbon atoms, a cycloalkylalkyl group having 4 to 7 carbon atoms, a cycloalkenylalkyl group having 5 to 7 carbon atoms, an aryl group having 6 to 12 carbon atoms, an aralkyl group having 7 to 13 carbon atoms, an alkenyl group having 3 to 7 carbon atoms, a furanylalkyl group (where the alkyl moiety has 1 to 5 carbon atoms), or a thiophenylalkyl group (where the alkyl moiety has 1 to 5 carbon atoms); R² and R³ are mutually independent and represent a hydrogen atom, a hydroxy group, an alkoxy group having 1 to 5 carbon atoms, an alkenyloxy group having 3 to 5 carbon atoms, an aralkyloxy group having 7 to 16 carbon atoms, an arylalkenyloxy group having 7 to 16 carbon atoms, an

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alkanoyloxy group having 2 to 6 carbon atoms, an alkenoyloxy group having 4 to 6 carbon atoms, an arylalkanoyloxy group having 7 to 16 carbon atoms, or an alkyloxyalkoxy group having 2 to 10 carbon atoms; R^4 and R^5 together form an $-O-$, $-S-$, or $-CH_2-$ bond, or are mutually independent and R^4 represents a hydrogen atom, a hydroxy group, an alkoxy group having 1 to 5 carbon atoms, or an alkanoyloxy group having 2 to 6 carbon atoms and R^5 represents a hydrogen atom; R^6 represents a hydrogen atom, an alkyl group having 1 to 5 carbon atoms, an alkenyl group having 2 to 6 carbon atoms, an arylalkyl group having 7 to 16 carbon atoms, an arylalkenyl group having 7 to 16 carbon atoms, a hydroxyalkyl group having 1 to 5 carbon atoms, an alkoxyalkyl group having 2 to 12 carbon atoms, a $COOH-$ group, or an alkoxy carbonyl group having 2 to 6 carbon atoms; and $-Q-$ moiety represents a group as follows:



(where these structures may have one or more substituents selected from the group consisting of a fluorine atom, a chlorine atom, a bromine atom, an iodine atom, a nitro group, an alkyl group having 1 to 5 carbon atoms, a hydroxyl group,

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an oxo group, an alkoxy group having 1 to 5 carbon atoms, a trifluoromethyl group, a trifluoromethoxy group, a cyano group, a phenyl group, a hydroxyalkyl group having 1 to 5 carbon atoms, an isothiocyanato group, SR^8 , SOR^8 , $SOOR^8$, $(CH_2)_rOR^8$, $(CH_2)_rCOOR^8$, $SOONR^9R^{10}$, $CONR^9R^{10}$, $(CH_2)_rNR^9R^{10}$, and $(CH_2)_rN(R^9)COR^{10}$ (where r is an integer from 0 to 5, R^8 represents an alkyl group having 1 to 5 carbon atoms, R^9 and R^{10} are mutually independent and represent a hydrogen atom, an alkyl group having 1 to 5 carbon atoms, or a cycloalkylalkyl group having 4 to 7 carbon atoms), and where X represents an oxygen atom, sulfur atom, a $CH=CH$, or NR^7 group (where R^7 represents a hydrogen atom, an alkyl group having 1 to 5 carbon atoms, an alkenyl group having 3 to 5 carbon atoms, an arylcarbonyl group having 7 to 13 carbon atoms, an alkylsulfonyl group having 1 to 5 carbon atoms, an arylsulfonyl group having 6 to 12 carbon atoms, an aralkylsulfonyl group having 7 to 13 carbon atoms, an aralkyl group having 7 to 16 carbon atoms, an arylalkenyl group having 7 to 16 carbon atoms, an alkanoyl group having 2 to 6 carbon atoms); Y represents a nitrogen atom or a CH group; and Z represents a bridge bond having 2 to 5 carbon atoms (where one or more carbon atoms may be replaced with a nitrogen, oxygen, or sulfur atom, and an aromatic or heteroaromatic ring having 5 to 12 carbon atoms or a cycloalkyl ring having 5 to 9 carbon atoms may be fused so as to share 2 or 3 skeletal carbon atoms)].

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Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Piperidine substituted compound

The following claim(s) are generic: to piperidines.

The species in the claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds of claim 2 clearly have different special technical features (i.e. the benzopyrrole or benzofuran derivatives) than that of the piperidine derivatives of claim 1, and neither the benzopyrrole or benzofuran derivatives of claim 2 nor piperidine derivative compounds in claim 1 define the contribution over the prior art. The substituents on the piperidine derivative vary extensively and when taken as a whole

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results in vastly different compounds. Accordingly, unity of the invention is considered to be lacking and consider proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter impose a burden on any examination of the claimed subject matter, therefore election is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembah whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
12/28/05


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600